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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/294,663
Filing Date	04/19/99
First Named Inventor	Granados et al
Group Art Unit	1638
Examiner Name	Ibrahim, M.
Total Number of Pages in This Submission	10
Attorney Docket Number	BTI-39CIP

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Response
  - ☐ After Final
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition Checklist and Accompanying Petition
- ☐ To Convert a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Additional Enclosure(s) *(please identify below)*:

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Brown & Michaels, PC
Signature	Thomas T. Aquilla
Date	9/17/01

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#16 BP 9/25/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

September 17, 2001

In re Application of:	Granados *et al.*
Serial No.	09/294,663
Filed:	April 19, 1999
For:	A NOVEL INVERTEBRATE INTESTINAL MUCIN cDNA AND RELATED PRODUCTS AND METHODS
Examiner:	Ibrahim, M.
Art Unit:	1638
Attorney Docket No.:	BTI-39-CIP

REPLY BRIEF UNDER 37 C.F.R. § 1.193(b)(1)

HONORABLE COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

This application is before the Honorable Board of Appeals on appeal from the Final Rejection by the Examiner dated December 12, 2000, wherein claims 1, 6 and 9 were finally rejected.

Under 37 C.F.R. § 1.193(b)(1), Appellant may file a reply brief directed to new points of argument raised in the examiner's answer, within two months of the date of such Answer. Appellant hereby submits its Reply Brief, in response to the new points of argument raised in the examiner's Answer, which was mailed on July 17, 2001.

CERTIFICATE OF MAILING

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Judy H. Barron

Judy H. Barron

(1)

NEW POINTS OF ARGUMENT RAISED IN EXAMINER'S ANSWER

In the Examiner's Answer, the Examiner argues that "The first step in obtaining a gene encoding a protein is to purify the protein, sequence the protein, and then design a nucleic acid hybridization probes (sic) which would encode part or all of the isolated, sequenced protein." Examiner's Answer, page 4, lines 16-19. The Examiner did not raise this argument in the Final Rejection, mailed December 12, 2000; this argument by the Examiner is raised for the first time in the Examiner's Answer.

Further, in regard to the ample data in Appellant's application, which provide guidance to one of ordinary skill in the art seeking to identify other genes that encode IIM proteins (including undiscovered genes) by teaching the use of the IIM antibody as a screening tool, the Examiner argues for the first time that "the crude protein preparations cast doubt on any data obtained by reacting antibodies thereto. Furthermore, the lack of purified protein for any non-*T. ni*-derived IIM protein would prohibit even the initial stages of gene isolation, as discussed above." Examiner's Answer, first complete paragraph on page 5. The Examiner did not raise these arguments in the Final Rejection, mailed December 12, 2000; these arguments by the Examiner are raised for the first time in the Examiner's Answer.

(2)

TRAVERSAL OF EXAMINER'S NEW POINTS OF ARGUMENT

The Examiner's assertion that "The first step in obtaining a gene encoding a protein is to purify the protein, sequence the protein, and then design a nucleic acid hybridization probes (sic) which would encode part or all of the isolated, sequenced protein" is factually incorrect. Contrary to the Examiner's assertion, it was well know in the art at the time of the present invention that one of ordinary skill can clone a gene without purifying the protein, sequencing the protein, or designing any nucleic acid hybridization probes whatsoever. See, *e.g.*, Sambrook, J., Fritsch, E.F. and Maniatis, T. (1989) Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, wherein it is taught that one can clone a gene by screening an expression library using an antibody, without purifying the protein, sequencing the protein, or designing any nucleic acid hybridization

probes. Indeed, Appellant cloned the *T. ni* IIM cDNAs disclosed in the present application by screening an expression library with the IIM antibody, according to methods that were well known in the art at the time of invention, and without any need for purifying the protein, sequencing the protein, or designing any nucleic acid hybridization probe whatsoever. The IIM antibody similarly could be used by one of ordinary skill in the art to identify and clone other cDNAs that encode IIM proteins, including undiscovered genes, without any need for purifying the protein, sequencing the protein, or designing any nucleic acid hybridization probe.

The Examiner's assertion that "the crude protein preparations cast doubt on any data obtained by reacting antibodies thereto. Furthermore, the lack of purified protein for any non-*T. ni*-derived IIM protein would prohibit even the initial stages of gene isolation, as discussed above" is not supported by any authority. Appellant traverses the Examiner's factual assertion that any "doubt" whatsoever reasonably could be cast upon Appellant's supporting data in the application, and in particular, data pertaining to the specificity of the IIM antibody. Indeed, there is no evidence of record casting any doubt whatsoever on Appellant's data, and, more particularly, there is no evidence that Appellant's IIM antibody is not specific for IIM protein. Thus, the Examiner's implication that the validity of Appellant's data is "doubtful" is traversed. Furthermore, the Examiner's assertion that "the lack of purified protein for any non-*T. ni*-derived IIM protein would prohibit even the initial stages of gene isolation" is traversed as being factually incorrect, as noted above.

Respectfully submitted:

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September 17, 2001